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| 09/839,185      | 04/19/2001  | Eduard Daniel Leendert Schmidt | S-30683A            | 1538             |

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EXAMINER

KUBELIK, ANNE R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 04/23/2003

124

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/839,185

Applicant(s)

SCHMIDT ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 3 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. The specification has been amended, claims 1-8 and 14 have been cancelled, and claims 9-13 have been amended, as requested in Paper No. 13, filed 3 February 2003.
2. The disclosure is objected to because it contains embedded hyperlinks and/or other forms of browser-executable code. See pg 8, line 10. Applicant is required to delete the embedded hyperlinks and/or other forms of browser-executable code. See MPEP § 608.01.
3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from pg 18, lines 11-12 and 14.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

4. The Office action of 29 July 2002 indicated that the drawings were objected to. However, the instant application does not have drawings, as pointed out by Applicant in the response filed 3 February 2003 (response pg 3).

### ***Response to Amendment***

5. The rejections of claims 1-9 and 14 under 35 USC 101 and 35 USC 112, first paragraph, because the claimed invention is not supported by a specifically asserted utility or a well-

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established utility is WITHDRAWN in light of cancellation or amendment of the claims.

6. The rejection of claims 10-12 under 35 USC 101 because the claimed invention is directed to non-statutory subject matter is WITHDRAWN in light of amendment of the claims.

7. The rejection of claims 1-2, 8-9 and 14 under 35 U.S.C. 102(b) as being anticipated by Schmidt et al in light of Shah et al is WITHDRAWN in light of cancellation or amendment of the claims.

#### ***Claim Objections***

8. Claims 9 and 12 are objected to because of the following informalities:

Claim 9 should be amended to replace "The" in line 1 with --A DNA construct comprising the--.

In claim 9, both instances of "The" in line 3, should be replaced with --the--.

In claim 12, there should be a comma after "10".

#### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The rejection is modified from the rejection set forth in the Office action mailed 29 July 2002, as applied to claims 1-9 and 12-14. Applicant's arguments filed 3 February 2003 have been fully considered but they are not persuasive.

The claims are broadly drawn to a nucleic acid encoding SEQ ID NO:2 and plants transformed with the nucleic acid.

The instant specification, however, only provides guidance for construction of a bait plasmid comprising the open reading frame of the *Arabidopsis* SERK gene, transformation into yeast and screening a *lexA* two hybrid library to isolate clones encoding 8 different classes of SERK-interacting proteins (example 1); identification of four of these classes as Squamosa-promoter binding protein (SBP) transcription factors, including clone 3A35 (SEQ ID NOs:1 and 2) and proposal that these are phosphorylated by SERK (example 2); and putative transformation of *Arabidopsis* with the clone (example 3).

The instant specification fails to teach a nucleic acid encoding SEQ ID NO:2 and plants transformed with the nucleic acid.

The nucleic acid indicated as encoding SEQ ID NO:2 cannot do so. SEQ ID NO:1 is only 551 nucleotides long, and is too short to encode the 375 amino acid long protein of SEQ ID NO:2. The specification teaches no other nucleic acids that could encode SEQ ID NO:2.

Additionally, just because a protein interacts with SERK in a yeast-two hybrid screen does not mean that plants transformed with a nucleic acid encoding that protein would be apomictic. One of the other classes of Squamosa-promoter binding protein (SBP) transcription factors isolated by the screen is SEQ ID NO:6 (specification, pg 17, paragraph 2). As discussed

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in the specification (pg 17, paragraph 2), this protein is involved in floral transition. Cardon et al (1997, Plant J. 12:367-377) teach that sense expression in *Arabidopsis* of a nucleic acid encoding this protein results in early flowering (pg 373, right column, paragraph 3, to pg 374, left column, paragraph 3) and antisense expression results in no change in plant phenotype. These plants are not apomictic.

Cardon et al (1999, Gene 237:91-104) teach that a nucleic acid that encodes a protein that differs from SEQ ID NO:2 by a single amino acid is expressed constitutively during *Arabidopsis* development. It is unlikely that a nucleic acid that encodes a protein that results in apomixes would be constitutively expressed during plant development.

The specification does not show that plants transformed with a nucleic acid encoding SEQ ID NO:2 are apomictic. Thus, it is not clear how to use the claimed nucleic acid.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled.

Applicant urges that claim 13 is drawn to a plant comprising a nucleic acid encoding SEQ ID NO:2, and that SEQ ID NO:1 is taught is the specification. Applicant also urges that transformation of plants is standard in the art. Furthermore, Applicant urges that the promoters in claim 9 are well-known in the art (response pg 4).

This is not found persuasive because SEQ ID NO:1 cannot encode SEQ ID NO:2, as discussed above. The previous Office action did not rejection the claims because plant transformation and the listed promoters are not enabled.

11. Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject

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matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is modified from the rejection set forth in the Office action mailed 29 July 2002, as applied to claims 1-9 and 12-14. Applicant's arguments filed 3 February 2003 have been fully considered but they are not persuasive.

The claims are broadly drawn to nucleic acids encoding SEQ ID NO:2. However, the specification fails to describe such a nucleic acid. The specification only describes a nucleic acid from *Arabidopsis* that comprises SEQ ID NO:1; this 551 nucleotide long nucleic acid is less than half the length required to encode a 375 amino acid long protein like SEQ ID NO:2. Applicant does not describe the DNA molecules encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Hence, Applicant has not, in fact, described DNA molecules that encode a SEQ ID NO:2, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

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a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Applicant urges that claim 12 has been amended to drawn to modification of a nucleic acid encoding SEQ ID NO:2 and that transformation of plants is standard. Furthermore, Applicant urges that the promoters in claim 9 are well-known in the art (response pg 5).

This is not found persuasive. The previous Office action did not rejection the claims because plant transformation and the listed promoters are not described.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 12 lacks antecedent basis for the limitation "the nucleotide sequence".

Claim 12 is awkward and confusing. It is suggested that the claim be amended to read as follows: --The isolated polynucleotide according to claim 10, wherein the polynucleotide is



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modified to remove mRNA instability motifs or polyadenylation signals and/or to use plant-preferred codons.--

14. Claims 9-13 are free of the prior art, given the failure of the prior art to teach or suggest an isolated nucleic acid encoding SEQ ID NO:2. The closest prior art is a nucleic acid from *Arabidopsis* (Rounsley et al, 1997, GenBank Accession No. AC002561) that encodes a protein that differs from SEQ ID NO:2 by one amino acid.

***Conclusion***

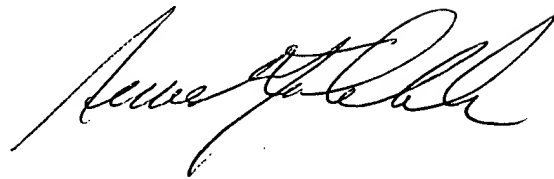
15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.  
April 16, 2003

A handwritten signature in black ink, appearing to read "Anne R. Kubelik", is written in a cursive style.